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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,364	06/09/2006	**Filippo G. Giancotti**	MSK.P-082	5691

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,364	GIANCOTTI, FILIPPO G.	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 13-24* is/are pending in the application.

4a) Of the above claim(s) *4,5,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,13-20,23 and 24* is/are rejected.

7)☒ Claim(s) *17 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Election filed January 29, 2009 in response to the Office Action of January 7, 2009 is acknowledged. Applicant elected with traverse the species of antibody therapeutic agents, breast cancer, and receptor protein tyrosine kinase Met. The species of receptor protein tyrosine kinases are **rejoined** for examination purposes.

2. Applicants state that this application is a 371 national phase application and argue that the unity of inventions standard must be applied. Applicants argue that when making lack of unity of invention restriction requirements, the Examiner must list the different groups of claim and explain why each group lacks unity with each other group. Applicants argue that the absence of a common inventive concept must be shown and not just the presence of differences. Applicants argue that as long as there is a single common special technical feature, a restriction requirement is improper. Applicants argue that the Examiner has not applied this standard correctly and has failed to describe why there is no common special technical feature. Applicants argue that the common inventive concept in claims 1 and 16 is the treatment of tumors by administration of a therapeutic agent that reduces the amount of active a6b4 and that all other claims are dependent on these claims and necessarily contain this special technical feature, hence the differences Examiner points out do not matter. Applicants argue that because there is a common special technical feature, restriction is improper (p. 5).

The arguments have been considered but are not found persuasive because Applicants are arguing a restriction of inventions which Examiner did not do. Examiner only restricted species and Applicants' arguments regarding a common special technical feature among inventions, listing separate groups, and explaining lack of unity among them do not apply to the species restriction. As explained in the restriction requirement, the species of cancers and therapeutic agents do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. In the case of therapeutic agents, each agent is structurally and functionally distinct, and because of their different structures and modes of operation, they lack the same or corresponding special technical features. In the case of different cancers, the abnormal cell types have different etiolologies, different structures, and different functions, all of which distinguish them as different tissues that would require different method steps to treat and criteria for success, hence they lack the same or corresponding special technical features. Applicants did not address Examiner's specific reasons for restricting species and the lack of the same or corresponding special technical features. For these reasons, the restriction requirement is deemed to be proper and is therefore made FINAL.

3. Claims 1-7 and 13-24 are pending. Claims 4, 5, 21 and 22 are withdrawn as being drawn to non-elected species. Claims 1-3, 6, 7, 13-20, 23, and 24 are currently being examined as drawn to the elected species of breast cancer and antibody therapeutic agent.

Claim Objections

4. Claims 17 and 24 are objected to because of the following informalities: Claims 17 and 24 recite "erbB2" while claims 13 and 15 recite "ErbB2". Examiner suggests capitalizing the "E" of "ErbB2" in all claims to maintain consistency. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6, 7, 13-20, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Application Publication 2003/0224993 A1, Land et al, filed March 17, 2003, published December 4, 2003 (IDS); as evidenced by Mercurio et al (Seminars in Cancer Biology, 2001, 11:129-141) and Lee et al (Clinical Cancer Research, 2005, 11:2222-2228).

The claims are drawn to a method for inhibition of initiation of primary or metastatic tumor growth in an individual suffering from or at risk for a tumor type that expresses a6b4 integrin, comprising the steps of administering to the individual a therapeutic agent effective to reduce the amount of active a6b4 integrin by targeting the beta 4 portion of the integrin, at least in a portion of the individual where initiation of primary or metastatic tumor growth may occur (claim 1), the method of claim 1, wherein

the individual is human (claim 2), the method of claim 2, wherein the therapeutic agent is an antibody (claim 3), the method of claim 2, wherein the individual is suffering from or at risk for a tumor type selected from the group consisting of breast and prostate cancers (claim 6), the method of claim 6, further comprising the step of administering to the individual an inhibitor of a receptor protein tyrosine kinase (claim 7), the method of claim 7, wherein the receptor protein tyrosine kinase is selected from the group consisting of ErbB2, EGF-R, Met and Ron (claim 13), the method of claim 2, further comprising the step of administering to the individual an inhibitor of a receptor protein tyrosine kinase (claim 14), the method of claim 14, wherein the receptor protein tyrosine kinase is selected from the group consisting of ErbB2, EGF-R, Met and Ron (claim 15), a method for inhibition of initiation of primary or metastatic tumor growth in an individual suffering from or at risk for a tumor type that expresses a6b4 integrin, comprising administering to the individual a therapeutic agent effective to reduce the amount of active a6b4 integrin by targeting the beta 4 portion of the integrin, at least in a portion of the individual where initiation of primary or metastatic tumor growth may occur by wherein the tumor expresses an amplified or activated version of a receptor protein kinase (claim 16), the method of claim 16, wherein the receptor protein kinase is selected from the group consisting of erbB2, EGF-R, Met and Ron (claim 17), the method of claim 16, wherein the individual is human (claim 18), the method of claim 18, wherein the tumor is breast cancer or prostate cancer (claim 19), the method of claim 18, wherein the therapeutic agent is an antibody (claim 20), the method of claim 18, further comprising the step of administering to the individual an inhibitor of a receptor

protein tyrosine kinase (claim 23), the method of claim 23, wherein the receptor protein tyrosine kinase is selected from the group consisting of erbB2, EGF-R, Met and Ron (claim 24).

Land et al teach a method of treating cancer in a patient comprising administering to the patient an antibody targeted to beta 4 to inhibit beta 4 integrin function or reduce the amount of active beta 4, wherein the administration is local to the cancer cells, wherein the patient is human, wherein the cancer is breast cancer ([0047-0089]; [0311-0334]; [0340]; claims 1, 2, 5, 10, 13, 15, 18, 34, 41, 45, 62, 65, 66, 91, 92, and 96-101), said method further comprising administering a receptor protein tyrosine kinase inhibitor, wherein the inhibitor inhibits EGFR or ErbB2 or is Herceptin®, wherein EGFR and ErbB2 are active in oncogenesis ([0313-0314]; [0334]; [0340]; claims 34, 41, 62, 91, and 97).

As evidenced by Mercurio et al, breast cancer expresses a6b4 (α6β4) (Table 1) and erbB2, wherein a6b4 associates with erbB2 in breast cancer (p. 135, col. 2). As evidenced by Lee et al breast cancer expresses MET (p. 2225, col. 2; Figure 2, Figure 3B, and Figure 4).

6. Claims 1, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Abdel-Ghany et al (J of Biological Chemistry, 2001, 276, 27:25438-25446), as evidenced by Lee et al (Clinical Cancer Research, 2005, 11:2222-2228).

The claims are drawn to a method for inhibition of initiation of primary or metastatic tumor growth in an individual suffering from or at risk for a tumor type that expresses a6b4 integrin, comprising the steps of administering to the individual a therapeutic agent effective to reduce the amount of active a6b4 integrin by targeting the beta 4 portion of the integrin, at least in a portion of the individual where initiation of primary or metastatic tumor growth may occur (claim 1), a method for inhibition of initiation of primary or metastatic tumor growth in an individual suffering from or at risk for a tumor type that expresses a6b4 integrin, comprising administering to the individual a therapeutic agent effective to reduce the amount of active a6b4 integrin by targeting the beta 4 portion of the integrin, at least in a portion of the individual where initiation of primary or metastatic tumor growth may occur by wherein the tumor expresses an amplified or activated version of a receptor protein kinase (claim 16), the method of claim 16, wherein the receptor protein kinase is selected from the group consisting of erbB2, EGF-R, Met and Ron (claim 17).

Abdel-Ghany et al teach a method of treating breast cancer in mice comprising administering an antibody that binds beta 4, wherein the breast cancer expresses α6β4 (abstract; p. 25439, col. 1; p. 25442, col. 2, first paragraph). The mice had breast cancer cells MDA-MB-231, and as evidenced by Lee et al, these cells overexpress tyrosine kinase receptor MET (abstract).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-3, 6, and 16-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-9, 15, 17, 19, 21-22 of copending **Application No. 10/595845**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application and the instant application are claiming common subject matter. The claims of both the copending application and the instant application are drawn to administering an antibody targeting beta 4 (β4) to a human who has a disease associated with angiogenesis, including breast cancer, wherein the breast cancer expresses α6β4.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. **Conclusion:** No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Primary Examiner, Art Unit 1642